REMARKS

Claims 1-3, 8-12, 14-17, 19, 20, 25-27, and 37 are currently pending. Claim 1 has been amended to incorporate claim 2, and claim 2 has been cancelled. Support for this amendment may be found, for example, in original claim 2.

Claims 1-3, 8-12, 14-17, 19, 20, 25-27, and 37[1] stand rejected under 35 U.S.C. §103(a) as unpatentable over WO 96/03113 ("WO '113") in view of Schwarz, U.S. Patent App. Pub. No. 2002/0102301 and Rouffer, U.S. Patent No. 6,221,391. The cancellation of claim 2 renders moot the rejection of that claim. Reconsideration of the rejection of claims 1, 3, 8-12, 14-17, 19, 20, 25-27, and 27 is respectfully requested.

As amended, claim 1 is directed to a self-emulsifying drug delivery system, wherein the system comprises, *inter alia*, polyvinylpyrrolidone ("PVP"), a fatty acid, and a surfactant in prescribed amounts. Claim 1 also prescribes weight ratios of fatty acid to PVP (from about 2:1 to about 1:3) and of surfactant to PVP (from about 10:1 to about 1:1).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP 2143.

The combination of WO '113, Schwarz, and Rouffer does not teach or suggest all the limitations of claim 1. Specifically, the combination of references does not teach or suggest the weight ratio of fatty acid to PVP (from about 2:1 to about 3:1) required by claim 1.

WO '113 describes oral compositions comprising a pharmaceutical, an emulsifier, an oil, and a solubilizer. As the Office acknowledges, WO '113 does not describe or suggest a composition comprising PVP. Thus, WO '113 does not describe or suggest the required fatty acid-to-PVP weight ratio.

Schwarz describes solid pharmaceutical compositions comprising a lipid phase, a surfactant system, a delivery control component, and excipients for tablet formation. One example of a suitable delivery control component is PVP. Schwarz's compositions may

[1] The Office Action indicates that claims 1-3, 6-20, 25-27, and 37 are rejected under §103(a). However, claims 6, 7, 13, and 18 were previously cancelled. Thus, the rejection of these claims appears to have been in error.

comprise a fatty acid such as oleic and linoleic acid. Schwarz states that "the type and level of excipients added to the self-emulsifying composition is also of high importance. Improper choice of these components leads to weak tablet formation or may make tablet preparation impossible." See ¶0016. However, Schwarz does not describe a composition having a fatty acid and PVP, and gives no guidance as to the amount of fatty acid suitable in his compositions. Thus, it is not possible to infer any teaching or suggestion of a fatty acid-to-PVP ratio from Schwarz.

Rouffer describes compositions comprising ibuprofen. These compositions may further comprise PVP. Rouffer says nothing about fatty acids (although his compositions may comprise fatty acid esters of glycol polyethylene glycol). Thus, Rouffer provides no suggstion or teaching of the required fatty acid-to-PVP ratio.

The combination of WO '113, Schwarz, and Rouffer does not teach or suggest all the limitations of claim 1. The Office has not established a *prima facie* case of obviousness with respect to this claim.

Likewise, the Office has not shown that dependent claims 3, 8-12, 14-17, 19, 20, 25-27, and 27 are *prima facie* obvious in light of WO '113 in view of Schwarz and Rouffer.

Applicants submit that the present invention is now in condition for allowance. Early allowance of all pending claims is respectfully solicited.

Respectfully submitted,

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